

## REMARKS

The specification has been amended to claim benefit of prior filed applications in accordance with 37 C.F.R. § 1.78(a)(2), to conform to current Patent Office practice requiring reference to the lettered subparts of the formal drawings submitted herewith, to correct typographical errors, to update the address of the American Type Culture Collection, to incorporate sequence identifiers pursuant to 37 C.F.R. § 1.821(d), to incorporate the Substitute Sequence Listing submitted herewith pursuant to 37 C.F.R. § 1.821(c) and renumber the pages of the claims accordingly. Additionally, the specification has been amended on page 5 to correct the location of the pentapeptide QACRG in SEQ ID NO:2. No new matter has been added.

A substitute sequence listing and substitute Figures 1A-B and 3A-C are submitted herewith to correct nucleotide and amino acid sequence errors as originally presented in the ICE-LAP 3 sequences (shown in the sequence listing as SEQ ID NOS:1 and 2). These changes do not introduce new matter because the correct sequence was inherent to the originally sequenced plasmid clone in actual possession of the Applicants before the time the captioned application was filed.

The captioned application is directed to both polynucleotides and polypeptides which are chemical compounds. The nucleotide sequence is but an inherent property of the described polynucleotides. There is a line of chemical case law where applicants have been permitted to amend the specification to correct the formula of a chemical compound after an application's filing date, provided that it had been demonstrated that one of skill in the art would have appreciated that the applicant was in possession of the compound itself at the time of filing. The rationale is that the formula is an inherent property of the compound and thus amending the specification to correct the formula is not new matter. See *In re Nathan*, 140 U.S.P.Q. 601, 604 (C.C.P.A. 1964). *Accord Kennecott Corp. v. Kyocera Int'l, Inc.*, 5 U.S.P.Q.2d 1194, 1198 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988) ("The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of the earlier filing date.").

In the field of biotechnology, applicants often rely on a deposited clone, where the deposit was made prior to filing, to establish possession of nucleic acids or proteins. The focus for determining whether applicants were in possession of claimed nucleic acids or proteins has been determined, at least in part, by considering whether the applicant has: (1) established that one skilled in the art in possession of the deposited clone would have been aware of both the DNA sequence and the encoded amino acid sequence, or would be able to determine these sequences without undue experimentation, (2) established that the DNA and amino acid sequences are described in a manner such that one skilled in the art could distinguish them from other sequences, and (3) resequenced a clone which is identical to that of the deposit and established a "chain of custody" for this clone. See

e.g., *Ex parte Maizel*, 27 U.S.P.Q.2d 1662, 1669-1670 (B.P.A.I. 1992).

Submitted herewith is a Declaration of Craig Rosen Under 37 CFR §1.132 (the "Rosen Declaration") which was filed in connection with the prosecution of parent application Serial Number 08/462,969, and which describes certain events involving the characterization of the nucleotide sequence of cDNA clone HE2CA82 which encodes ICE-LAP 3. The HE2CA82 cDNA clone was deposited with the American Type Culture Collection (ATCC) on August 25, 1994; i.e., prior to the filing date of parent application US Serial No. 08/334,251 (filed November 1, 1994). Exhibit A of the Rosen Declaration is a copy of the contract for ATCC Deposit No. 75875. The Examiner will note that the present specification states on page 5, lines 7 and 8, that ATCC Deposit No. 75875 contains the cDNA which encodes ICE-LAP 3.

The corrected nucleic acid and deduced amino acid sequences (shown in replacement Figures 1 and 3 submitted herewith) were determined by reanalyzing cDNA clone HE2CA82 (ATCC Accession No. 75875); i.e., the same cDNA clone from which the originally presented sequences were determined (see paragraph 4 of the Rosen Declaration). The corrected sequence information was published by the present inventors in a peer-reviewed scientific journal article (see Exhibit B of the Rosen Declaration).

The analysis needed to determine the complete and correct sequences of cDNA clone HE2CA82 were well within the skill of the ordinary artisan as of the filing date of the parent application US Serial No. 08/334,251 (filed November 1, 1994), and such analysis would not have required undue experimentation (see paragraph 5 of the Rosen Declaration).

Exhibit D of the Rosen Declaration shows the four (4) nucleotide differences between the original sequence ("PF140" in the Exhibit) and the corrected sequence ("Duan" in the Exhibit).

In summary, because Applicants have demonstrated that the corrected sequences are inherently present in the deposited material, and because Applicants have demonstrated "chain of custody" for the material originally sequenced and the resequenced material, correction of the originally presented sequence information herein is not new matter.

#### **Statement Under 37 C.F.R. §§ 1.821(e) and (f)**

The above-identified patent application is a divisional of application Serial No. 08/462,969, filed June 5, 1995. The content of the paper copy of the Substitute Sequence Listing filed herewith is identical to the sequence content of the computer readable sequence listing previously filed on March 22, 1999 in connection with application Serial No. 08/462,969.

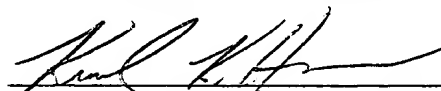
In accordance with 37 C.F.R. § 1.821(e), please use the computer readable form filed on March 22, 1999 in connection with application Serial No. 08/462,969 as the

computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Substitute Sequence Listing is being filed herewith. Applicants hereby certify that the paper copy of the Substitute Sequence Listing filed herewith and the computer readable sequence listing previously filed in connection with application Serial No. 08/462,969 on March 22, 1999 are the same and do not include new matter.

Applicants respectfully request that the amendments and remarks above be entered and made of record in the file history of the instant application.

Respectfully submitted,

Dated: July 10, 2000

  
Kenley K. Hoover (Reg. No. 40,302)  
Attorney for Applicants

**Human Genome Sciences, Inc.**  
9410 Key West Avenue  
Rockville, MD 20850  
Telephone: (301)

Enclosure